

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PROTHERICS, INC.

5214 Maryland Way
Brentwood, TN 37027

Plaintiff,

v.

HON. DAVID KAPPOS,
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office.
Office of General Counsel, United States
Patent and Trademark Office,

Madison Building East, Rm. 10B20
600 Dulany Street,
Alexandria, Virginia 22314

Defendant.

CIVIL ACTION NO.: _____

COMPLAINT UNDER 35 U.S.C. § 145
TO AUTHORIZE THE DIRECTOR TO ISSUE LETTERS PATENT

Plaintiff, Protherics, Inc. ("Protherics"), by and through its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This case concerns a ground-breaking treatment for rattlesnake venom poisoning and the erroneous denial by the United States Patent & Trademark Office ("PTO") of patent protection for that technology. Protherics is the assignee of U.S. Patent Application Serial No. 08/405,454 ("the '454 application") and is dissatisfied with a decision by the Board of Patent Appeals and Interferences ("the Board"). Protherics seeks judgment, pursuant to 35 U.S.C. § 145, that it is entitled to a patent.

THE PARTIES

2. The plaintiff, Protherics, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business at 5214 Maryland Way, Brentwood, TN 37027.

3. The defendant is the Honorable David Kappos, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the PTO, having offices at 600 Dulany Street, Alexandria, Virginia 22314.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action and is authorized to issue the requested relief pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 145; and 5 U.S.C. §§ 701-706.

5. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) and 35 U.S.C. § 145.

6. This Complaint is being timely filed in accordance with 35 U.S.C. § 145 and 37 C.F.R. § 1.304(a).

GENERAL ALLEGATIONS

7. Dr. John B. Sullivan and Dr. Findlay E. Russell are toxicology experts who spent decades treating and studying snake poisoning. They developed a new treatment for rattlesnake venom poisoning. The antivenom treatment they developed uses Fab antibody fragments and has been commercialized as the drug CroFab®.

8. The treatment that Dr. Sullivan and Dr. Russell developed is described and claimed in the '454 application, titled (as amended) "Antivenom Composition Containing FAB Fragments."

9. Protherics is the sole owner of the '454 application. Protherics acquired all right, title, and interest in the '454 application by virtue of an assignment by and from the application's sole inventors, Dr. Sullivan and Dr. Russell.

10. The '454 application was filed in the PTO on March 15, 1995. As presently amended, the '454 application contains claims 40-42 and 50.

11. The '454 application is a continuation of U.S. Patent Application Serial No. 08/277,288 ("the '288 application"), which was filed in the PTO on July 22, 1994 and was pending as of the March 15, 1995 filing date of the '454 application.

12. The '288 application is a continuation of U.S. Patent Application Serial No. 08/124,438 ("the '438 application"), which was filed in the PTO on September 22, 1993 and was pending as of the July 22, 1994 filing date of the '288 application.

13. The '438 application is a continuation of U.S. Patent Application Serial No. 07/593,271 ("the '271 application"), which was filed in the PTO on October 1, 1990 and was pending as of the September 22, 1993 filing date of the '438 application.

14. The '271 application is a divisional of U.S. Patent Application Serial No. 07/378,925 ("the '925 application"), which was filed in the PTO on July 12, 1989 and was pending as of the October 1, 1990 filing date of the '271 application.

15. The '925 application is a divisional of U.S. Patent Application Serial No. 06/659,629, which was filed in the PTO on October 9, 1984 and was pending as of the July 12, 1989 filing date of the '925 application.

16. Claims 40-42, 50, and 54-55 are pending in the '454 application. Claims 40-42 and 50 of the '454 application are directed to an antivenom pharmaceutical composition for treating a snakebite victim comprising Fab fragments. Claims 54-55 are directed to a method of treating envenomation by a snake comprising administering the antivenom pharmaceutical composition of claims 40-42 and 50.

17. On or about June 4, 2003, the PTO Examiner issued two separate final rejections of claims 40-42 and 50 of the '454 application as being unpatentable under 35 U.S.C. § 103(a). In the first of those rejections, the PTO Examiner cited and relied upon the following references: (a) J.B. Sullivan, Jr. and F.E. Russell, "Isolation and Purification of Antibodies to Rattlesnake Venom by Affinity Chromatography," *Proc. West. Pharmacol. Soc.* 25: 185-92 (1982) ("Sullivan article"); and (b) Alan Coulter and Rodney Harris, "Simplified Preparation of Rabbit Fab Fragments," *Journal of Immunological Methods*, 59:199-203 (1983) ("Coulter article"). In the second of those rejections, the PTO Examiner cited and relied upon (a) the Sullivan article; (b) the Coulter article; (c) T.W. Smith et al., "Immunogenicity and Kinetics of Distribution and Elimination of Sheep Digoxin-Specific IgG and Fab Fragments in the Rabbit and Baboon," *Clin exp. Immunol.* 36:384-96 (1979) ("Smith article"); and (d) *Stedman's Medical Dictionary*, Twenty-Third Edition (1976).

18. On or about June 4, 2003, the PTO Examiner withdrew claims 54-55 of the '454 application from consideration. The PTO Examiner withdrew method claims 54-55 from consideration on the theory that they were drawn to a different invention than the composition claims, which had been the subject of earlier prosecution of the '454 application and thus constructively elected.

19. The '454 applicants duly and timely appealed from the PTO Examiner's rejection to the Board, under 35 U.S.C. § 134(a). On or about March 30, 2006, the Board issued a Decision on Appeal wherein it sustained and affirmed the rejection of claims 40-42 and 50 under 35 U.S.C. § 103(a) as being obvious over the Sullivan article in view of the Coulter article.

20. The '454 applicants in turn duly and timely appealed from the Board's decision to the Court of Appeals for the Federal Circuit, under 35 U.S.C. § 141. On August 29, 2007, the Federal Circuit vacated the Board's decision on the ground that the Board had erroneously failed to consider expert declarations indicating, *inter alia*, that a person of ordinary skill in the art would have expected an antivenom comprising Fab antibodies fragments to increase the lethality of rattlesnake venom rather than reduce it. A copy of the Federal Circuit's decision is attached hereto as Exhibit A.

21. On or about October 22, 2007, the Federal Circuit's mandate issued, and the application was returned to the Board for further consideration.

22. On or about June 15, 2009, the Board issued another Decision on Appeal that again affirmed the PTO Examiner's rejection of claims 40-42 and 50 under 35 U.S.C. § 103(a) as being obvious over the combination of the Sullivan article and the Coulter article. The Board also affirmed the PTO Examiner's rejection of claims 40-42 and 50 under 35 U.S.C. § 103(a) as being obvious over the combination of the Sullivan article, the Coulter article, the Smith article, and Stedman's Medical Dictionary. A copy of the Board's Decision on Appeal is attached hereto as Exhibit B.

23. The PTO made reversible errors of fact and law during its administrative examination and review of the '454 application. Specifically, the PTO erred in rejecting the '454 application's pending claims under 35 U.S.C. § 103(a) as being obvious over the Sullivan article in view of the Coulter article as well as the Sullivan article in view of the Coulter article, the Smith article, and Stedman's Medical Dictionary. The PTO's errors included a failure to apply correct legal standards for obviousness during its examination and review, and a failure to give proper consideration to the evidence of record.

24. Additional evidence not of record in the PTO further confirms that claims 40-42 and 50 of the '454 application comply with 35 U.S.C. § 103(a) and should therefore be allowed. For example, and without limitation, soon after CroFab® (*i.e.*, a product embodying the invention) was first marketed in the United States, the only other commercially-available rattlesnake antivenom was withdrawn from the market because it caused many side effects and was less safe than CroFab®. The life-saving properties of CroFab® have been featured on a multi-part program for the television series "Animal ER." CroFab® is projected to have sales in the U.S. of over US\$30 million in 2009.

25. Plaintiff has not appealed to the United States Court of Appeals for the Federal Circuit from the Board's most recent Decision on Appeal. This complaint is being filed within two months of the Board's Decision on Appeal and in accordance with 35 U.S.C. § 145 and 37 C.F.R. § 1.304(a).

26. Claims 40-42 and 50 of the '454 application satisfy the applicable statutory and regulatory requirements and are patentable. As assignee of the '454 application, Protherics is entitled to an issued patent for the invention claimed in the '454 application.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that Judgment be entered for Plaintiff, and that Plaintiff be granted the following relief:

A. Judgment that the PTO erred in concluding that the '454 application does not satisfy the requirements of the Patent Statute, 35 U.S.C. § 1 et seq.

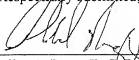
B. Judgment that Plaintiff is entitled to receive a Letters Patent for the invention as described and claimed in the '454 application, in due form of law as prescribed by the Patent Statute, Title 35, United States Code, § 1 et seq.

C. Judgment pursuant to Title 35, United States Code, § 145, authorizing the Director of the United States Patent and Trademark Office to issue a Letters Patent on the invention described and claimed in the '454 application in due form of law and as prescribed by the Patent Statute, Title 35, United States Code, § 1 et seq.

D. Such other and further relief as this Court may deem just and proper.

Dated: 08/13/2009

Respectfully submitted,



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